

REMARKS

Claims 15-20 are pending in the application. Claims 1-14 and 21-58 are withdrawn. Claims 15-20 are rejected under 35 U.S.C. §102 for lack of novelty; under 35 U.S.C. §112, first paragraph, for lack of written description; and under 35 U.S.C. §112, second paragraph, as being indefinite.

Restriction Election

Applicants hereby request that methods of producing s-CPG-15 compositions of matter be rejoined.

Claim Amendments

Claims 15, 16, 18, and 20 are amended, claim 17 is withdrawn, claims 19, 24-28, 30, 32, 35-37, and 40 are cancelled, and new claims 59-70 are added. Support for the amendment to claims 15, 16, 18, and 20 is found throughout the specification, for example, at p. 6, lines 11-25; p. 12, lines 6-8; p. 13, lines 7-9; p. 26, lines 4-10; and p. 39, line 26 - p. 40, line 24. Support for new claims 59-70 is found, for example, at p. 12, lines 6-8, and p. 28, lines 3-8.

No new matter has been added by the present amendment. Applicants reserve the right to pursue any withdrawn subject matter in this or in a continuing application.

Rejection under 35 U.S.C. §102

Claims 15-20 are rejected under 35 U.S.C. §102 as being unpatentable over Zhou et al. (5 April 2000, Accession No. AAF62371; hereafter “Zhou”), Naeve et al. (Proc. Nat. Acad. Sci. U.S.A. 94:2648-2653, 1997; hereafter “Naeve”), and Nedivi et al. (Science 281:1863-1866, 1998; hereafter “Nedivi”). Zhou, Naeve, and Nedivi each disclose a polypeptide sequence corresponding to the full-length CPG-15 protein, which bears 100% sequence identity over residues 28-114 to SEQ ID NO: 1.

Naeve discloses the sequence of the full-length CPG-15 protein (see, Figure 1A, p. 2650), which is identical to the sequence of Zhou and Nedivi. Naeve further describes the full-length or mature CPG-15 protein as a “membrane-bound protein” (p. 2649, right column, paragraph 4) that is “attached to the cell surface by a GPI-lipid group” (p. 2650, left column, paragraph 2). Therefore, Naeve teaches full-length CPG-15 protein is not soluble. All of the presently amended claims require that the claimed CPG-15 protein is soluble.

Therefore, as Zhou, Naeve, and Nedivi fail to disclose the invention, i.e., a soluble CPG-15 protein having the ability to promote cell survival, to promote cell differentiation, or to prevent or reduce cell death, the Applicants respectfully request that the present rejection be removed.

Rejections under 35 U.S.C. §112, first paragraph

Claims 15-18 and 20 are rejected for undue breadth under 35 U.S.C. §112, first paragraph. The Office states:

In re Hyatt, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. (Office Action, page 4.)

The M.P.E.P. §2164.01(b) states:

As long as the specification discloses *at least one* method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. (Emphasis added.)

The Applicants teach several methods for the production of purified soluble CPG-15 in the specification. The present specification teaches recombinant expression vectors encoding CPG-15; transfection or infection of a variety of host cells with these expression vectors; and purification of the expressed *soluble* CPG-15 protein from the supernatant of host cells (see, for example, pg. 24, line 12 - pg. 27, line 19). Furthermore, Applicants teach assays for testing the biological activity of a purified *soluble* CPG-15 protein (see, for example, p. 42, line 15 - p. 45, line 3). In addition, Applicants demonstrate purification of a soluble CPG-15 protein of the invention from the culture medium of

293T cells transfected with a CPG15-FLAG expression plasmid (see, Examples 3, 4, and 7 of the specification).

Therefore, as Applicants teach a number of ways of making and using the soluble CPG-15 protein of the invention, the rejection should be withdrawn.

Claims 15-18 and 20 are also rejected under 35 U.S.C. §112, first paragraph, for lack of written description. The Office states:

[T]he specification does not teach functional or structural characteristics of all peptides “having s-CPG15 biological activity.” The description of one polypeptide (SEQ ID NO: 1) that does have s-CPG15 activity is not adequate written description of an entire genus of functionally equivalent polypeptides. (Office Action, p. 5.)

Applicants have amended claim 15 to specify a purified soluble CPG-15 polypeptide comprising a sequence with at least 85% sequence identity to SEQ ID NO: 1 and having one biological activity from the following group: the ability to promote cell survival, the ability to promote cell differentiation, and the ability to prevent or reduce cell death. Therefore, the Applicants respectfully request that the rejection be removed.

Rejections under 35 U.S.C. §112, second paragraph

Claims 15-20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office states:

[I]t is unclear what is meant by the recited biological activity. A claim is indefinite where it merely recites an activity for a polypeptide, without further delineating the identifying characteristics of that polypeptide. (Office Action, page 7).

As described above, Applicants have amended claim 15 to specify the structural characteristics and the activity of the claimed peptides. Therefore, the rejection of claim 15, and those dependent thereon, should be withdrawn.

Claims 15-20 are also rejected under 35 U.S.C. §112, second paragraph, as being indefinite, for reciting the term “s-CPG-15.” Applicants have amended claim 15 to state “soluble Candidate Plasticity Gene-15 (s-CPG-15).” The rejection can now be withdrawn.

Claim 18 is further rejected under 35 U.S.C. §112, second paragraph, as being indefinite, because it recites “(b) a CPG15 protein bound to a cell membrane and the CPG15 protein released from the cell” (Office Action, p. 7.) Claim 18 has been amended to state:

CPG15 protein has undergone all of the following modifications:
a) the signal sequence and the GPI linkage sequence of said CPG15 protein have been cleaved;
b) said CPG15 protein has been bound to a cell membrane; and
c) said CPG15 protein has been released from the cell into the supernatant...

The rejection should now be removed.

CONCLUSION

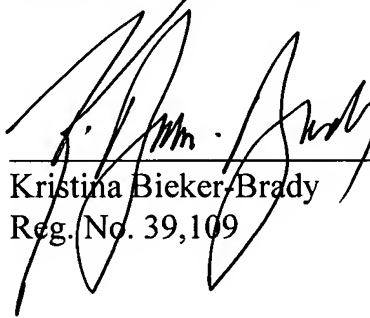
Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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